

## § 524.900

## 21 CFR Ch. I (4–1–05 Edition)

(d) *Conditions of use*—(1) *Amount*. One milliliter (5 milligrams) per 10 kilograms of body weight (500 micrograms per kilogram).

(2) *Indications for use*. The drug is used in beef and dairy cattle for treatment and control of gastrointestinal roundworms (*Haemonchus placei* (adult and L4), *Ostertagia ostertagi* (adult and L4, including inhibited L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *T. longispicularis* (adult), *Cooperia oncophora* (adult and L4), *C. punctata* (adult and L4), *C. surnabada* (adult and L4), *Nematodirus helvetianus* (adult and L4), *Bunostomum phlebotomum* (adult and L4), *Oesophagostomum radiatum* (adult and L4), *Strongyloides papillosus* (adults), *Trichuris* spp. (adults)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (all parasitic stages *Hypoderma lineatum*, *H. bovis*); lice (*Damalinia bovis*, *Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*); mange mites (*Chorioptes bovis*, *Sarcoptes scabiei*); and horn flies (*Haematobia irritans*). Controls and protects from reinfection of *D. viviparus* for 21 days after treatment and *H. irritans* for 7 days after treatment.

(3) *Limitations*. Apply topically along backbone from withers to tailhead. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[62 FR 33997, June 24, 1997, as amended at 63 FR 59715, Nov. 5, 1998]

## § 524.900 Famphur.

(a) *Chemical name*. O,O-Dimethyl O-[p-(dimethylsulfamoyl)phenyl] phosphorothioate.

(b) *Specifications*. The drug is in liquid form containing 13.2 percent famphur.

(c) *Sponsor*. See Nos. 000061 and 051311 in § 510.600(c) of this chapter.

(d) *Special considerations*. Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(e) *Related tolerances*. See § 556.273 of this chapter.

(f) *Conditions of use*. (1) The drug is used as a pour-on formulation for the control of cattle grubs and to reduce cattle lice infestations.

(2) It is used at the rate of 1 ounce per 200 pounds body weight, not to exceed a total dosage of 4 ounces, applied from the shoulder to the tail head as a single treatment. It is applied as soon as possible after heel fly activity ceases. Do not use on lactating dairy cows or dry dairy cows within 21 days of freshening, calves less than 3 months old, animals stressed from castration, over-excitement or dehorning, sick or convalescent animals. Animals may become dehydrated and under stress following shipment. Do not treat until they are in good condition. Brahman and Brahman crossbreeds are less tolerant of cholinesterase-inhibiting insecticides than other breeds. Do not treat Brahman bulls.

(3) Do not slaughter within 35 days after treatment. Swine should be eliminated from area where run-off occurs.

[40 FR 13873, Mar. 27, 1975, as amended at 49 FR 34352, Aug. 30, 1984; 57 FR 7652, Mar. 4, 1992; 59 FR 28769, June 3, 1994; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997; 69 FR 41427, July 9, 2004]

## § 524.920 Fenthion.

(a) *Chemical name*. O,O-Dimethyl O-[4-(methylthio)-m-tolyl] phosphorothioate.

(b) *Specifications*. (1) The drug is in a liquid form containing 3 percent of fenthion.

(2) *Sponsor*. See No. 000859 in § 510.600(c) of this chapter.

(3) *Special considerations*. Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(4) *Related tolerances*. See 40 CFR 180.214.

(5) *Conditions of use*. (i) The drug is used as a pour-on formulation for the control of grubs and lice in beef and nonlactating cattle.

(ii) It is used at the rate of one-half fluid ounce per 100 pounds of body weight placed on the backline of the animal. Only one application per season should be made for grub control and this will also provide initial control of lice. A second application for lice control may be made if animals become reinfested, but no sooner than 35 days after the first treatment. Proper timing of treatment is important for

grub control; cattle should be treated as soon as possible after heel-fly activity ceases. Cattle should not be slaughtered within 35 days following a single treatment. If a second application is made for lice control, cattle should not be slaughtered within 45 days of the second treatment. The drug must not be used within 28 days of freshening of dairy cattle. If freshening should occur within 28 days after treatment, do not use milk as human food for the balance of the 28-day interval. Do not treat lactating dairy cattle; calves less than 3 months old; or sick, convalescent, or stressed livestock. Do not treat cattle for 10 days before or after shipping, weaning, or dehorning or after exposure to contagious infectious diseases.

(c) *Specifications.* (1) The drug is in a liquid form containing 20 percent fenthion.

(2) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(3) *Special considerations.* Do not use on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

(4) *Related tolerances.* See 40 CFR 180.214.

(5) *Conditions of use.* (i) The drug is used for control of cattle grubs and as an aid in controlling lice on beef cattle and on dairy cattle not of breeding age.

(ii) It is applied as a single application placed on the backline of animals as follows:

Weight of animal	Dosage (milliliters)
150 to 300 lb .....	4
301 to 600 lb .....	8
601 to 900 lb .....	12
901 to 1,200 lb .....	16
Over 1,200 lb .....	20

For most effective results, cattle should be treated as soon as possible after heel-fly activity ceases. Host-parasite reactions such as bloat, salivation, staggering and paralysis may sometimes occur when cattle are treated while the common cattle grub (*Hypoderma lineatum*) is in the gullet, or while the northern cattle grub (*H. bovis*) is in the area of the spinal cord. Cattle should be treated before these stages of grub development. Consult your veterinarian, extension livestock

specialist, or extension entomologist regarding the timing of treatment. If it is impossible to determine the area from which the cattle came and/or exact stage of the grubs, it is recommended that the cattle receive only a maintenance ration of low-energy feed during the treatment period. This lessens the likelihood of severe bloat which may occur in cattle on full feed when the common grub is killed while in the gullet. A second application is required for animals heavily infested with lice or for those which become re-infested. A second application should be made no sooner than 35 days after the first treatment.

(iii) Do not treat dairy cattle of breeding age; calves less than 3 months old; sick, convalescent, or severely stressed livestock.

(iv) Do not treat cattle for 10 days before or after shipping, weaning, dehorning, or after exposure to contagious or infectious diseases.

(v) Do not slaughter within 45 days of treatment.

(d) *Specifications.* (1) The drug is a solution containing either 5.6 or 13.8 percent fenthion. Each concentration is available in 2 volumes which are contained in single-dose applicators.

(2) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(3) *Special considerations.* Fenthion is a cholinesterase inhibitor. Do not use this product on dogs simultaneously with or within 14 days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use with flea or tick collars.

(4) *Conditions of use—(i) Amount.* Four to 8 milligrams per kilogram of body weight.

(ii) *Indications for use.* For flea control on dogs only.

(iii) *Limitations.* Apply the contents of the proper size, single-dose tube directly to one spot on the dog's skin. Frequency of repeat treatments depends upon rate of flea reinfestations. Do not use more often than once every 2 weeks. Treatment at 2-week intervals is not to exceed 6 months. Do not use on puppies under 10 weeks of age. Do not use on sick, stressed, or convalescing dogs. Safe use in breeding males has not been established. Federal

## § 524.960

law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 41 FR 16656, Apr. 21, 1976; 42 FR 58741, Nov. 11, 1977; 45 FR 62425, Sept. 19, 1980; 50 FR 19169, May 7, 1985]

### § 524.960 Flumethasone, neomycin sulfate, and polymyxin B sulfate ophthalmic solutions.

(a) *Specifications.* Each milliliter of ophthalmic preparation contains 0.10 milligram flumethasone, 5.0 milligrams neomycin sulfate (3.5 milligrams neomycin base), and 10,000 units of polymyxin B sulfate, with or without hydroxypropyl methylcellulose.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*—(i) *Preparation containing hydroxypropyl methylcellulose.* Dogs: 1 to 2 drops per eye, every 6 hours.

(ii) *Preparation without hydroxypropyl methylcellulose.* Dogs and cats: 2 to 3 drops per eye, every 4 hours.

(2) *Indications for use.* Treatment of the inflammation, edema, and secondary bacterial infections associated with topical ophthalmological conditions of the eye such as corneal injuries, incipient pannus, superficial keratitis, conjunctivitis, acute nongranulomatous anterior uveitis, keratoconjunctivitis, and blepharitis.

(3) *Limitations.* (i) In treating ophthalmological conditions associated with bacterial infections, the drug is contraindicated in those cases in which microorganisms are not susceptible to the antibiotics incorporated in the drug.

(ii) The drug is contraindicated in infectious tuberculous lesions of the eye, early acute stages of viral diseases of the cornea and conjunctiva, herpes simplex lesions of the eye, and fungal infections of the conjunctiva and eyelids.

(iii) The usual precautions and contraindications for corticosteroids and adrenocorticoids are applicable with this drug. Corticosteroids may inhibit essential inflammatory responses intrinsic to the fundamental healing mechanism. Adrenocorticoid compounds have been reported to cause an increase in intraocular pressure. Intraocular pressure should be checked fre-

## 21 CFR Ch. I (4–1–05 Edition)

quently. Ocular reexaminations should be made at frequent intervals during long-term therapy.

(iv) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[44 FR 16012, Mar. 16, 1979, as amended at 61 FR 5507, Feb. 13, 1996]

### § 524.981 Fluocinolone acetonide ophthalmic and topical dosage forms.

#### § 524.981a Fluocinolone acetonide cream.

(a) *Specifications.* The drug contains 0.025 percent fluocinolone acetonide.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the relief of pruritus and inflammation associated with certain superficial acute and chronic dermatoses in dogs. It is used in the treatment of allergic and acute moist dermatitis and for the relief of superficial inflammation caused by chemical and physical abrasions and burns.

(2) A small amount is applied to the affected area two or three times daily.

(3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 40932, July 31, 1997]

#### § 524.981b Fluocinolone acetonide solution.

(a) *Specifications.* The drug contains 0.01 percent fluocinolone acetonide in propylene glycol with citric acid.

(b) *Sponsor.* See No. 099207 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the relief of pruritus and inflammation associated with otitis externa and certain superficial acute and chronic dermatoses in the dog. It is also indicated for the relief of pruritus and inflammation associated with acute otitis externa and certain superficial acute and chronic dermatoses in the cat.

(2) A small amount of solution is applied to the affected area 2 or 3 times daily.